Evaluation of measuring HIV-1 viral load in self-sampled blood.

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The objectives of this study are:1) Assessing the user-friendliness of a self-sampling technique.2) Assessing the quality of the self-collected sample (volume and composition).3) To estimate the degree of agreement between viral loads in the self-...

Ethical review	Approved WMO
Status	Pending
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON56653

Source
ToetsingOnline

Brief title
Measuring HIV-1 viral load in self-sampled blood.

Condition

- Viral infectious disorders

Synonym
HIV infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: HIV-1, self-sampling, viral load

Outcome measures

Primary outcome

• Agreement in viral loads between:

o self-sampled HemoLink and conventional viral load measurement.

Secondary outcome

• Sample quality (volume and clots)

• User friendliness scores

• Laboratory logistics

Study description

Background summary

The majority of people living with HIV in the Netherlands who are receiving treatment for it are in good and stable health. Nevertheless, they are usually seen at the outpatient clinic twice a year for an appointment with their HIV treatment team and for monitoring of HIV in their blood. For people with well-treated HIV and stable health, an appointment with their treatment team once a year, alternated with a self sampled blood test at home after 6 months, to determine the amount of viral load could be sufficient. On the one hand, this would save people living with HIV time and effort, and on the other hand it would lead to efficient use of the limited resources available for HIV care. However, it is unclear whether self-sampling of blood at home to determine the amount of viral load is practically feasible and reliable enough. Proposed research aims to answer these questions.

Study objective

The objectives of this study are:

1) Assessing the user-friendliness of a self-sampling technique.
2) Assessing the quality of the self-collected sample (volume and composition).
3) To estimate the degree of agreement between viral loads in the

self-collected sample and in the conventional hospital-collected sample.

Study design

Validation study with single routine clinic visit at Amsterdam UMC:

• Regular visit to HIV outpatient clinic & conventional viral load measurement
• Consenting participants are provided with the system for self-sampling of blood.
• Participants are asked to self-sample at home and send the sample to the laboratory on the same day.
• Participants are asked to complete a brief questionnaire about convenience of the self- sampling technique.

Study burden and risks

Risks are minimal. Home-based self-sampling is safe with clear instructions. Filling in a brief questionnaire about the user-friendliness of self-sampling is of minimal burden..

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• adult (aged >= 18 years) living with HIV
• speak Dutch or English
• provide written informed consent

We will include 2 groups of participants. Additional inclusion criteria in the 2 groups are:

1. Prolonged viral suppression group (n=14):
• stable on ART
• viral load suppressed for more than 2 years
• without comorbidities requiring more than one clinic visit per year

2. Persistent low level viremia group (n=30)
• receiving ART
• known to have low level viremia (200 -400 copies/ mL range).

Exclusion criteria

• No informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2024
Enrollment:	44
Type:	Anticipated

Medical products/devices used

Generic name:	TassoOne Plus
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-03-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL83917.018.23